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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/986,426	11/08/2001	Randal J. Kirk	54719.000011	5236
7590 10/20/2004			EXAMINER	
Hunton & Williams Suite 1200 1900 K Street, NW Washington, DC 20006			WARE, DEBORAH K	
			ART UNIT	PAPER NUMBER
			1651	
DATE MAILED: 10/20/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

## Application No.

09/986,426

## Applicant(s)

KIRK ET AL.

## Examiner

Deborah K. Ware

## Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 7/13/04
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 53-54 <sup>d 63-107</sup> is/are pending in the application.
- 4a) Of the above claim(s) 70-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 5 is/are allowed.
- 6) ☒ Claim(s) 54, 57-61, 62-75 & 75-107 is/are rejected.
- 7) ☐ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s)        are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on        is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No.       .
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

Art Unit: 1651

### **DETAILED ACTION**

Claims 54, 57-61, and 63-107 are presented for examination on the merits.

Claims 76-94 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention(s), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 26, 2004.

This application contains claims 76-94 drawn to an invention nonelected with traverse in Paper No. 02262004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 54, 57-61, 63-75 and 95-107 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims are rendered vague and indefinite for the recitation of "non-covalently protected" because it is unclear what this is intended to mean in the claims per se.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 59-60, 62, 66, 71 and 95-107 are rejected under 35 U.S.C. 102(b) as being anticipated by Peterson et al for reasons of record.

Applicant's arguments filed July 13, 2004, have been fully considered but they are not persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., non-covalent attachment) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

***Claim Rejections - 35 USC § 103***

Claims 57-58, 61, 63-65, 67-70, 72-75 and 95-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al in view of Latham et al ('227) and Kramer et al, all cited on previously submitted PTO-1449 Form and of record.

Applicant's arguments filed July 13, 2004, have been fully considered but they are not persuasive because the argument that the claims are newly limited to non-covalent attachment is noted but the claims are not directed to attachment per se. The claims are directed to non-covalent protection. Peterson et al clearly

teach that depending upon the solubility of the bioactive agent the polymeric carriers must be altered to achieve optimum release rate. For example, for delivery of hydrophilic drugs, the polymeric backbone must be made hydrophobic; and of course the opposite is also true. Therefore, for hydrophilic drugs, the polymeric bone can be expected to be made hydrophilic in order to obtain an optimum release rate. Further, the polymer can be diminished in hydrophilicity or even made hydrophobic by the inclusion of amino acids, like alanine, leucine and valine, etc., into the backbone which provides for a variety of copolymeric systems. Note column 4, line 9-25. Thus, it would have been at least obvious to one of ordinary skill in the art at the time the claimed invention was made to provide for non-covalent protection given the optimum conditions required for the bioactive agent and its' corresponding release rate. The motivation in the cited prior art can be derived from its teachings with respect to optimum requirements and the motivation to provide for a variety of copolymeric systems. Thus, to select for a non-covalent bond or to protect an agent as such using these bonds is well within the skill of an ordinary artisan and further one of skill would be motivated to optimize the copolymeric systems as needed.

The claims remain prima facie obvious over the cited prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1651

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deborah K. Ware  
September 30, 2004



DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT 1651